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10/595,450	06/21/2007	Hasan B. Alam	101672.0071P	9092
34284	7590	10/01/2010	EXAMINER	
Rutan & Tucker, LLP. 611 ANTON BLVD SUITE 1400 COSTA MESA, CA 92626			TREYGER, IL'YA Y	
			ART UNIT	PAPER NUMBER
			3761	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,450

Applicant(s)

ALAM ET AL.

Examiner

ILYA Y. TREYGER

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 12, 13, 16 and 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-11, 14, 15, 17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 3-5, 12, 13, 16 and 18 are canceled.
2. Claims 1, 2, and 6-11, 14, 15, 17 and 19-25 are examined on the merits.

Response to Arguments

Applicant's arguments filed 07/09/2010 have been fully considered but they are not persuasive:

3. With respect to claims 1, 17, 19 and 24, Applicants argue that the element 10a of Pena (fig. 1) is not a manually operable pump as cited by the Examiner in the last Office Action.

Examiner apologies for misinterpretation of the Pena's element 10a. However, Pena expressly discloses a manually operable pump means including an elastic bulb adapted to be manually compressed, the manually operable pump comprising a pair of one-way valves respectively situated at the suction inlet and pressure outlet for providing for flow of fluid only from the suction tubular means into the elastic bulb during expansion of the latter and for flow of fluid only out of said elastic bulb into said pressure tubular means during manual compression of said elastic bulb (Col. 2, lines 14-26; Col. 6, lines 43-53), wherein a pair of one-way valves are providing one-way flow (Col. 2, lines 21-26).

4. Applicants further argue that the combination of references is improper because there are no teachings or suggestions in Pena that the device of Pena might be used with respect to another portion of the body, other than nasal cavity.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where

there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, since the nasal fossae is the variation of body cavity, the ability of the apparatus of being used with respect to one body cavity is the straight motivation to use the apparatus with respect to another body cavity if desired.

5. Applicants further argue that the combination of references is improper because the reference discloses that the device is "adapted for positioning in the nasal fossae" and therefore teaches away from the proposed combination, i.e. to be connected to another device that may be used in another portion of the body.

However, being used in the nasal fossae does not preclude the device from being capable of connection to another device that may be used in another portion of the body. As such the reference does not teach away from the proposed combination of references.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

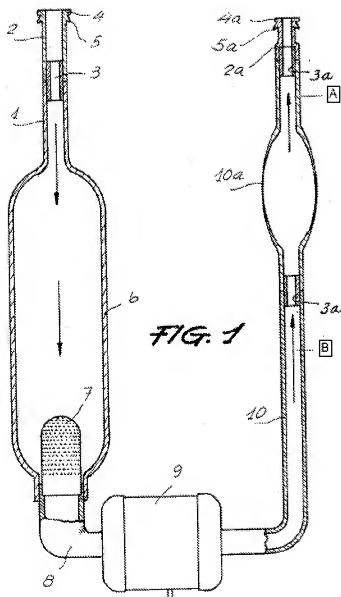
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
9. Claims 1, 2, 6-11, 14, 15, 17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pena (US 4,029,095) in view of Schachet (US 3,783,870).
10. In Re claim 1, Pena discloses device for circulating treating fluid through the nasal fossae, which is a body cavity, comprising:

a manually operable pump means including an elastic bulb adapted to be manually compressed, the manually operable pump comprising a pair of one-way valves respectively situated at the suction inlet and pressure outlet for providing for flow of fluid only from the suction tubular means into the elastic bulb during expansion of the latter and for flow of fluid only out of said elastic bulb into said pressure tubular means during manual compression of said elastic bulb (Col. 2, lines 14-26; Col. 6, lines 43-53), wherein a pair of one-way valves are providing one-way flow (Col. 2, lines 21-26), and therefore is fully capable of providing the flow by gravity alone if positioned vertically;

an inflow conduit B and outflow conduit A connected to the bulb by connectors 3a (Fig.

1); and

. Inflow connector (4).



Pena does not expressly disclose the apparatus comprising a pleural evacuation tube for removing fluid from a plural space but discloses cannula 2 comprising a flange 4 being adapted

for positioning into the nasal fossa. As such, Pena motivates those skilled in the art to attach any type of tubing being adapted for positioning into the any particular body cavity.

Schachet teaches the suction drainage device (See Title) for connection to a pleural cavity (Abstract, lines 1-2) comprising a pleural evacuation tube for removing fluid from a pleural cavity (col. 3, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to supply the device of Pena with the pleural evacuation tube, as taught by Schachet in order to in order to remove fluids from the pleural space (Schachet, col. 1, lines 8-11).

11. In Re claim 2, Pena discloses the manual pump wherein the inflow conduit is selected from the group consisting of a standard chest tube, an endotracheal tube, and/or a catheter, since both a standard chest tube, an endotracheal tube, and/or a catheter are variations of the conduit.

12. In Re claims 6-8, Pena discloses the manual pump comprising the bulb 10a fully capable of being compressed by one hand (claim 6), two hands (claim 7), or by using foot (claim 8) (See Fig. 1).

13. In Re claim 9, Pena discloses the manually operable pump wherein the exterior of the compressible portion is covered by a textured surface. In accordance with definition the texture is the appearance and feel of a surface (See *The American Heritage® Dictionary of the English Language, Fourth Edition*). Since the pump body 10a is disclosed as operated by the hand it is designed to be felt, and thus the pump body surface is textured.

14. In Re claim 10, Pena discloses a manually operable pump fully capable of removing a body fluid components, since the apparatus of Pena is disclosed as intended to remove liquid from the nasal cavity and comprises the same structure, as claimed by Applicants.

15. In Re claim 11, Pena discloses the manually operable pump connected to the external device 9 (Fig. 1), and thus is fully capable of being connected to an autotransfusion device.

16. In Re claim 14, Pena discloses the manually operable pump comprising a conduit 10 (Fig. 1) fully capable of being connected to the additional manually operable pump.

17. In Re claim 15, Pena in view of Schachet disclose the claimed invention discussed above, but do not expressly disclose the particular parameter of the negative pressure range generating by the pump.

The particular parameter of the negative pressure range generating by the pump depends of the particular quantity of liquid intended to be removed from the body cavity, and therefore is a result effective variable and a matter of optimization.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pump generating the negative pressure range depending of the particular quantity of liquid intended to be removed from the body cavity, since discovering the optimum or workable ranges involves only routine skill in the art.

18.

19. In Re claim 17, Pena discloses device for circulating treating fluid through the nasal fossae, which is a body cavity, comprising:

a manually operable pump means including an elastic bulb adapted to be manually compressed, the manually operable pump comprising a pair of one-way valves respectively

situated at the suction inlet and pressure outlet for providing for flow of fluid only from the suction tubular means into the elastic bulb during expansion of the latter and for flow of fluid only out of said elastic bulb into said pressure tubular means during manual compression of said elastic bulb (Col. 2, lines 14-26; Col. 6, lines 43-53), wherein a pair of one-way valves are providing one-way flow (Col. 2, lines 21-26), and therefore is fully capable of providing the flow by gravity alone if positioned vertically;

an inflow conduit B and outflow conduit A connected to the bulb by connectors 3a (Fig. 1); and

. Inflow connector (4).

Pena does not expressly disclose the apparatus comprising a pleural evacuation tube for removing fluid from a plural space.

Schachet teaches the suction drainage device (See Title) for connection to a pleural cavity (Abstract, lines 1-2) comprising a pleural evacuation tube for removing fluid from a pleural cavity (col. 3, lines 19-22).

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

20. In Re claims 19 and 20, Pena discloses the system for removing fluids from a body cavity, comprising:

a fluid receptacle 6 (Col. 2, line 64; Figs. 1 and 2) fully capable of receiving fluids from the body cavity; and

a manually operable pump in fluid communication with both the body cavity and the fluid receptacle, operation of the pump generating a negative pressure relative to the body cavity

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(Col. 2, lines 14-26; Col. 6, lines 43-53), wherein the manually operable pump comprises a pump body having a pair of one-way valves respectively situated at the suction inlet and pressure outlet for providing for flow of fluid only from the suction tubular means into the elastic bulb during expansion of the latter and for flow of fluid only out of said elastic bulb into said pressure tubular means during manual compression of said elastic bulb (Col. 2, lines 21-26) (claim 20), wherein a pair of one-way valves are providing one-way flow (Col. 2, lines 21-26), and therefore is fully capable of providing the flow by gravity alone if positioned vertically.

Schachet teaches the suction drainage device (See Title) for connection to a pleural cavity (Abstract, lines 1-2) comprising a pleural evacuation tube for removing fluid from a pleural cavity (col. 3, lines 19-22).

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

21. In Re claim 21, Pena discloses the system comprising a tube A (Fig. 3) which is interpreted as a implantable catheter, since it is disposed into the nasal cavity.
22. In Re claim 22, Pena discloses the system comprising two connectors 3a (Fig. 2) connecting conduits 2a and 10 to the appropriate ends of the pump body 10 (Fig. 2).
23. In Re claim 23, Pena in view of Schachet disclose the claimed invention discussed above, but do not expressly disclose the particular parameter of the fluid flow range generating by the pump.

The particular parameter of the fluid flow range generating by the pump depends of the particular disease intended to be treated and the particular type of treatment required, and therefore is the matter of optimization.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pump generating the fluid flow range depending of the particular clinical diagnosis and treatment required, since discovering the optimum or workable ranges involves only routine skill in the art.

24. In Re claim 24, since the system of Pena is disclosed as provided and assembled, Pena discloses the method of removing fluid from a nasal fossae fully capable of producing the same result removing fluid from a pleural cavity, the method comprising:

attaching a manually operable pump to a proximal end of an implanted catheter, the manually operable pump in fluid communication with a fluid receptacle;

generating a negative pressure via the manually operable pump to initiate fluid flow from the body cavity toward the fluid receptacle; and

positioning the manually operable pump to flow fluid from the body cavity to the fluid receptacle with the aid of gravity.

Pena does not expressly disclose the method comprising a device having a pleural evacuation tube for removing fluid from the plural space.

Schachet teaches the method of draining the pleural cavity (Abstract, lines 1-2) using the apparatus having a pleural evacuation tube for removing fluid from a pleural cavity (col. 3, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Pena by providing the pleural evacuation tube, as taught by Schachet in order to focus the method to draining liquid from the particular body cavity, i.e. pleural cavity (Schachet, col. 1, lines 8-11).

25. In Re claim 25, Pena discloses the step of generating a negative pressure comprises compressing a pump body interposed between two one-way valves to initiate unidirectional fluid flow from the body cavity to the fluid receptacle (Col. 2, lines 14-26; Col. 6, lines 43-53).

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ilya Y Treyger/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit
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